SUMMARY OF THE PROFICIENCY TESTING COMMITTEE MEETING JANUARY 12-13, 1999

The Proficiency Testing Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, January 12, 1999, at 1:30 p.m. Eastern Standard Time (EST) and on Wednesday, January 13, 1999, at 9 a.m. EST as part of the Fourth NELAC Interim Meeting in Bethesda, Maryland. The meeting was led by its chair, Ms. Anne Rhyne of the Texas Natural Resources Conservation Commission. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to review and discuss proposed changes to Chapter 2 and its appendices and to discuss the issue of whether a State should be able to choose providers for the laboratories in its accreditation program.*

INTRODUCTION

Ms. Rhyne began the meeting by introducing Ms. Reenie Parris, Mr. Bob Graves, and Ms. Betsy Dutrow who work closely with the committee. Committee members introduced themselves and provided some individual background. Ms. Rhyne also reviewed ground rules for the meeting. She asked that commentors prepare written comments and submit them to the committee by March 28, 1999, which is the deadline set by the NELAC Board of Directors. Committee members then reviewed changes to their assigned sections of the chapter.

Sections 2.1 thru 2.3 (Ms. Cindy Nettrour)

There was a question about Section 2.3.2.1 regarding the analytes included in a sample. Mr. Graves clarified the intent of the proposed regulations in the Federal Register. If a laboratory correctly reports a zero result, then that result is equivalent to the quantitative analysis of an analyte present in the sample. A random selection of analytes, meeting the required number to be present, has been prescribed so that the laboratories are not prevented from switching proficiency testing (PT) providers. Mr. Graves said that the EPA *National Standards for Water Proficiency Testing/Criteria Document* does contain language to describe which analytes can be left out. The committee will discuss this issue with Mr. Graves further at a later date and may propose revisions to the NELAC Standards accordingly.

Another person asked whether inductively coupled plasma/mass spectrometry (ICP/MS) was considered a multi-component analyte. Mr. Wibby responded that it is not.

Section 2.1 will be modified to clarify the scope of rules and make sure all appendices are referenced.

Sections 2.4 thru 2.7 (Darlene Raiford)

A participant asked how NELAC would assure that laboratories analyzed PT samples using "routine" methods. There was concern that laboratories might treat the PT samples in a special manner (e.g., run multiple analyses, use multiple methods, etc.). The committee responded that those performing on-site assessment (inspections) will be responsible for evaluating whether a lab

treated a PT sample differently from a routine sample. Laboratories are expected to treat PT samples the same way they would a sample coming in with an unknown history. In the future, laboratories may be given data quality objectives in advance which should cut down on laboratories running multiple analyses. It was noted that laboratories will stand a good chance of passing their PT sample performance evaluations if their instruments are calibrated correctly.

Ms. Raiford explained that text has been added to Section 2.7.3 to specify that a laboratory must report analyses for samples designated as NELAC PT samples. If a lab does not report results for such samples, then they are counted as deficiencies. The laboratory may purchase samples and not designate them as a NELAC samples.

Section 2.7.6 will be revised to read:

A p~~P~~rimary accrediting authority~~ies~~ may specify which months that laboratories within its authority are required to participate in NELAP PT programs. ~~The months which the~~ If the primary accrediting authorit~~ies~~y chooses to specify the months, then it shall adhere to the required semiannual schedule. If the primary accrediting authority does not specify the months, ~~taken~~ then the laboratory shall determine the schedule.

It was questioned whether, under mitigating circumstances, there is a mechanism which allows laboratories to withdraw from reporting results for a NELAC-designated PT sample after it has been ordered. The committee acknowledged that there are various circumstances for which a laboratory should be allowed to withdraw from a study without it being counted as a failed study. It was commented that the ultimate decision should be in the hands of the primary accrediting authority. Another comment was that both the provider and the accrediting authority should be notified when a laboratory is withdrawing from a study, and this must be done before the closing date of the study. This may be done only for situations where the labortory is not required to participate. Ms. Rhyne proposed to add a new Section 2.7.7 entitled "Withdrawal from PT Studies." Committee members agreed. The language for this section will need to be coordinated with the Accrediting Authority Committee.

Someone asked whether a laboratory that uses more than one method to analyze an analyte, has to run a PT sample for each method. The committee said "No." A laboratory will choose one method and notify the accrediting authority which method(s) they want to be accredited for. Analysis of PT samples by one method is prescribed in order to keep the cost to laboratories low.

Proficiency testing challenges the laboratory's quality system. PT is just one aspect of the laboratory evaluation. Quality Systems requires an initial demonstration of capability for all methods used, and the on-site assessment should review the laboratory's quality system.

Rotation of methods used for PTs was brought up as a possible solution to eventually include all the methods used by a laboratory. A committee member said that this may be over-prescriptive. Another idea was to require that a laboratory repeat analysis by the same method if they fail a PT for an analyte. These ideas have been tabled for further discussion at a later time. It was agreed, however, that the provider should report the method to the accrediting authority.

The third sentence in Section 2.6 will be revised to read:

The PT study provider shall provide the participant laboratories and the primary accrediting authority a report showing at a minimum the laboratory's reported value, the prepared value, the acceptance range, ~~and~~ the acceptable/not acceptable status, and the method for each analyte reported by the laboratory.

Some discussion ensued about the capabilities of the national database. Mr. Graves said that the database is set up to store one method code, per analyte, per sample. However, the national database is a secondary repository for the PT data. The primary databases will be maintained by the accrediting authorities.

Appendix A (Tom Coyner)

Mr. Coyner explained that text has been deleted from Section A.6.0 because EPA has decided to publish the acceptance ranges. Therefore, there is no reason to require that providers keep this information from disclosure.

It was asked what to call EPA's National Standards within the NELAC standards. Mr. Graves said that because the standards are in draft form, and have not yet been assigned a document number, EPA uses the full title "National Standards for Water Proficiency Testing Studies/Criteria Document." Chapter 2, Section A.4.0 (and any other occurrences) will be edited to be consistent with this title.

Appendix B (Chuck Wibby)

Mr. Wibby explained that Section B.5.3 has been added in order to give States an avenue for receiving uniform results from PT providers.

It was commented that some of the material in other appendices may also apply to microbiology. The committee agreed that this may be true, and agreed to look into it further.

Appendix C (Chuck Wibby)

Mr. Wibby reviewed changes to Appendix C. He said that the committee intends to include a better definition for interdependent analytes at a later date.

Appendix D (Barbara Burmeister)

Ms. Burmeister said that a comparison had been made between Chapter 2 and the National Institute of Standards and Technology (NIST) and EPA documents. Changes were made to Appendix D so that there is consistency between documents.

Appendix E (Matt Caruso)

Mr. Caruso reviewed minor changes in Appendix E. It was requested that the committee modify Section E.1.1 to clarify whether the sample is reconstituted. The committee agreed to do this.

A commentor recommended that the acceptance criteria be modified to include a positive result ("no false positives") on a blank. Mr. Caruso said that this was considered.

Appendix F (Chuck Wibby)

A new draft for Appendix F (Radiochemistry) was distributed at the meeting. Mr. Wibby said that basically, this document is the EPA's National Standards for Radiochemistry with some editorial changes. One of the committee's primary goals was to make the NELAC standards consistent with EPA standards and this is a starting place. A complete appendix will be included in the proposed chapter at NELAC V. Mr. Wibby summarized each section of the new appendix.

Comments that were made included:

One participant stated that a history is not needed; training is outside of our scope; licensing is not needed; dilutions will cause problems; percentages are preferred over control limits. Another commenter said that she does not think this should be a reinvention of an old program. A lot of justification has gone into NELAC's decision for requiring PT samples twice a year. If this requirement is going to be different for radiochemistry (three times per year), then there should be some technical justification included. She strongly suggested that development of this appendix be a joint effort between NELAC and EPA.

Appendix G (Jim Horne standing in for Faust Parker)

Mr. Horne said that this document is similar to the current DMRQA document. A major change being recommended is a reduction in the number of options that are in the current DMRQA. He thinks that a lot more work needs to be done on penalties.

A commentor said that references to on-site assessments should not be included here. The committee will look into references to on-site assessments throughout the chapter and remove them. This will be done in coordination with the On-site Assessment Committee.

Appendix H (Lara Autry)

Ms. Autry reviewed the new draft Appendix H on Air. This appendix was distributed at the meeting. The subcommittee that developed this appendix is a subgroup of the Field Sampling Committee. There is currently no agreement between EPA and NIST to provide Standard Reference Materials (SRMs) and accredit for air samples. Ms. Autry pointed out that NIST may elect not to include air samples as part of their program. She also pointed out that air is very different from water. The appendix will need to address all the differences for air samples from the standards set up for water. She asked anyone with comments or interest in working on this appendix to please contact her.

Ms. Rhyne acknowledged that the expansion of the PT program into additional matrices (solid waste and air) is an issue, and asked that it be added to the list of items to be addressed in the future.

Issue Consideration: Should a State Choose PT Provider(s)? (Tom Coyner)

A handout was distributed which explains some of the background, key assumptions involved, and several scenarios. One of the key assumptions is that the market operates to control quality. Once NELAC takes effect, it will have a tremendous impact on a laboratory's business. Mr. Coyner said that there are two key issues which need to be discussed. First, who will the laboratory contrac,t with and who does the laboratory have recourse to? Second, who will invalidate data? NIST has said that they cannot invalidate data and previously EPA only provided this function for their own studies. Similarly, the responsibility for invalidation shall lie with each provider.

Some of the key issues discussed were: market forces, reciprocity between states, invalidation of samples, need for an oversight board or central referee body, State's administration of its program, and needs of small laboratories versus large laboratories. Some of the comments and suggestions brought up at the meeting are listed below. It was agreed by the committee to discuss this issue further.

Market Forces

A commentor argued that NELAC should allow laboratories to choose their PT providers. He said that market forces will operate to help control the problems.

A commentor pointed out that we are dealing with interstate commerce. He challenged the committee to get legal guidance in dealing with this issue. Another commenter stated that three areas of law need to be explored: Federal-Federal, Federal-State, and State-State to explore the interstate commerce.

Reciprocity Between States

Someone asked what criteria a State would use to select a provider. How would this affect reciprocity? Another commentor said that he does not think State selection causes a problem for reciprocity and that it is an issue only within the primary state. If a laboratory is accredited, then another State must accept their data.

Invalidation of Samples

It was asked whether a State can invalidate samples. A response was that if a state can declare samples invalid, then it will cause problems in reciprocity with other states. NIST cannot invalidate samples. The only one who can do this is the provider.

Another commenter suggested that NELAC could specify the criteria for acceptance or dismissal of a sample. The PT Committee has previously considered this option and determined that there will be situations which the committee cannot foresee. Therefore, the committee is leaving it up to the provider to determine some matters on a case-by-case basis.

Oversight Board or Central Referee Body

A State representative said that he does not have a problem with multiple providers. However, he thought there would be an oversight board. He said that the sense is that strong oversight responsibilities are slipping away. Ms. Reenie Parris said that NIST is going to be providing oversight of the program, as well as EPA, which will be looking at the data for different reasons. Mr. Coyner pointed out that because NIST cannot invalidate samples, the only recourse NIST will have is to remove accreditation of providers.

Several participants agreed that they would like to have some kind of central referee for the entire nation.

State Administration of its Program

Several commentors expressed their preference for allowing States to select their provider. Some of the reasons follow. A commentor said that right now the Sstates have a close relationship with all the laboratories that have primacy with them. It is critical to have a good relationship. He asked that NELAC not tell the States how to administer their program. He thinks that States should provide guidance to laboratories in selection of the PT provider. Another commentor said that the individual States should be allowed to select their own provider, and deal with the consequences. He added that multiplicity of providers compounds the length of time to complete the studies. A State commentor said that States should not have to accept just any provider. They want to have confidence in the program. If the States cannot have confidence in the provider, they may choose not to participate in NELAC.

A State representative pointed out that states have the right to set the schedule, to write to their laboratories to let them know what they need to be accredited for, to specify the format for the data reported to them, etc. He said that he is very comfortable with what he has heard from NIST and does not have a problem with laboratories selecting their own provider.

It was pointed out that if the State does select the provider, they will still need to decide whether to accept data from other providers. The laboratories will have to analyze two PTs before the States can select the provider.

It was proposed from the floor that States be allowed to administer their program, but laboratories should still have freedom of choice of their provider. Ms. Darlene Raiford agreed that a compromise is needed.

It was suggested that NELAC fine-tune a series of options. Let the laboratories choose to go to a provider of their own choice or choose to get their samples from their state. If a laboratory seeking accreditation goes to a NIST-accredited provider, with all the checks and balances in the system, why wouldn't a State accept those results?

Needs of Small Laboratories vs. Large Laboratories

A commenter from a small laboratory said that their samples are currently provided by their State. With all the problems faced daily, this is their one security blanket. The commentor said that she thinks the States should provide samples. Allow the States to decide which options they want to give their laboratories based on options that NELAC can provide for them.

Another commenter said that fields of testing have influence in this decision. Specialty fields of testing should be considered.

Federal Facilities

It was asked where federal facilities go if a state selects the provider?

Federal Register Notice (Anne Rhyne)

Ms. Rhyne explained that EPA issued a Federal Register Notice on July 31, 1998 which requires that once a year, laboratories run a PT for each method for which compliance monitoring is done (for drinking water samples). EPA is currently responding to comments. Once this is done, it will be proposed as a final rule. Ms. Rhyne said that the NELAC PT standards have not been changed to incorporate this yet. However, when it becomes a final rule, the additional requirement will have to be added to the NELAC Standards for drinking water samples. She pointed out that although NELAC does require PTs twice a year, the requirement to run a PT for all methods is only once per year (the second PT only has to be run using the "routine" method).

Other Discussions

A participant asked about the prioritized analyte list. Committee members said that the list is available. Ms. Rhyne asked for business cards for those interested in receiving a copy of the prioritized analyte list and said that the list would be sent out to them.

A participant commented that other chapters should add language to refer to Chapter 2 when they discuss performance testing. In addition, some corrections need to be made to other chapters to be consistent with Chapter 2. For example, Chapter 4 includes "program/method/analyte" when it should read "program/matrix/analyte." The PT Committee agreed to discuss this issue with the other committees.

Attachment A

ACTION ITEMS
PROFICIENCY TESTING COMMITTEE MEETING
JANUARY 12-13, 1999

Item No.	Action	Date to be Completed
1.	Discuss whether a state shall accept data from any NELAP-approved provider.	NELAC V
2.	Clarify Section 2.1 to include reference to all new appendices.	NELAC V
3.	In Microbiology Appendix, include references to verification of micro strains.	NELAC V
4.	Discuss analyzing non-detect PT samples.	NELAC V
5.	Remove references to on-site assessments. Coordinate with On-Site Assessment Committee.	NELAC V
6.	Expand PT Provider Accreditation and PT standards to include solid waste and air programs.	Ongoing

Attachment B

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PROFICIENCY TESTING COMMITTEE MEETING
JANUARY 12-13, 1999

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